510(k) SUMMARY

SUBMITTER:	Dideco S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 011 39 0535 29811 Fax: 011 39 0535 25229
DATE PREPARED:	April 7, 2005
DEVICE TRADE NAME:	ECC.O: System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Hollow Fiber Oxygenator and Heat Exchanger
COMMON NAMES:	Hollow Fiber Oxygenator with Integrated Heat Exchanger Venous Defoamer Centrifugal Blood Pump
CLASSIFICATION NAMES:	Cardiopulmonary Bypass Oxygenator. Cardiopulmonary Bypass Heat Exchanger Cardiopulmonary Bypass Defoamer Non-Roller Type cardiopulmonary Bypass Blood Pump
UNMODIFIED DEVICE	D 905 EOS Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir (K043323)
PREDICATE DEVICE:	Ideal Mimesys' Centrifugal Pump (K032040) cleared also independently as Cobe Cardiovascular Revolution Centrifugal Blood Pump with PC coating (K030462) Ideal Mimesys' Venous Air Removal Device (K 032040) Ideal Mimesys (K032040) System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Adult Membrane Oxygenator, Heat Exchanger and Arterial Filter (K032040), with phosphorylcholine coating.

DEVICE DESCRIPTION:

The ECC.O System with Integrated Venous Air Removal Device, Centrifugal Blood Pump, Pump Bracket, Hollow Fiber Oxygenator and Heat Exchanger is an extracorporeal hemodynamic and gas exchange support system for extracorporeal perfusion. ECC.O consists of a high efficiency, microporous, hollow fiber membrane oxygenator integrated with a heat exchanger connected to a venous air removal device (defoamer) (Ideal Mimesys' Venous Air Removal Device, K032040), a centrifugal pump (Ideal Mimesys' Centrifugal Pump, K032040) and a pump bracket.

INDICATION FOR USE:

The ECC.O System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Hollow Fiber Oxygenator and Heat Exchanger The ECC.O is intended for use in patients who undergo surgical procedures requiring extracorporeal gas exchange support and blood temperature control with a maximum blood flow rate of 5 liters/minute. ECC.O must not be used longer than 6 hours. Contact with blood for longer periods is inadvisable. ECC.O is intended for use with the Stöckert Centrifugal Pump Console.

TECHNOLOGICAL CHARACTERISTICS:

The ECC.O is comprised of a hollow fiber oxygenator with an integrated heat exchanger identical to the D 905 EOS unmodified device. The only modifications made to the device consist of a combination of the Ideal Mimesys' Bubble Trap and Centrifugal Pump to the oxygenating module of the D 905 EOS Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir (K043323), updating of the product specifications in the IFUs and change in the Ph.I.S.I.O. trade name. The basic function of all integrated defoamer/oxygenators is the same. The function is a combination blood gas exchange device with a dedicated active venous air removal section (defoamer). The basic function of all centrifugal pumps is the same, that is, moving blood through the cardiopulmonary bypass circuit by centrifugal force. The operating principles and fundamental scientific technology is unchanged from the unmodified The ECC.O duplicates the functionality of the separate predicate devices and the indications for use is unchanged as a result of the combination. The coating is identical to the phosphorylcholine coating used on the D 905 EOS unmodified and Ideal Mimesys' Bubble Trap and Centrifugal Pump predicate devices.
The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

NONCLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1:1995 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials. Tests were performed on devices accelerated aged to an equivalent of three years real time aging.–The D 905 EOS device was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. The Ideal Mimesys was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Biocompatibility testing performed on D 905 EOS and Ideal Mimesys predicate devices have been taken as reference for the ECC.O system as the raw materials used in the manufacturing process are identical to those used in both predicate devices. Sterility, Pyrogenicity, ETO residuals and package integrity testing were also conducted. The results of this testing met established specifications.

***IN VITRO* TEST RESULTS:**

In vitro testing was carried out in accordance with the requirements of the "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff" issued on November 13, 2000 – "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000 and when applicable, following the ISO 7199 standard for "cardiovascular Implants and Artificial Organs – Extra Corporeal Blood gas Exchangers (Oxygenator)" for providing the data necessary to demonstrate both the substantial equivalence with the unmodified/predicate devices and compliance with safety and effectiveness requirements. The ECC.O aged up to 3 years was tested for hemolysis/cell depletion, operating blood volume, mechanical integrity, flaking and leaching study characterization and air handling characterization. The results of these tests met established specifications. For comparative purposes the same testing, when applicable, has been conducted also on the D 905 EOS assembled in a circuit with the Ideal Mimesys' Bubble Trap and Centrifugal Pump. The modifications being made to the ECC.O do not affect the performance of the device; therefore, the functional and biocompatibility parameters exhibited by D 905 EOS apply to the ECC.O.

CONCLUSION:

The ECC.O system is substantially equivalent to the unmodified device. Additional testing has also demonstrated the effectiveness of production techniques to assure that the oxygenator is sterile and non-pyrogenic.

Previous *in-vitro* data showed that the ECC.O performs in a manner substantially equivalent to the D 905 EOS with respect to the expected main performance parameters associated with ordinary oxygenators with integrated heat exchanger that is transfer of oxygen and removal of carbon dioxide, blood temperature control.

Furthermore, the ECC.O performs in a manner substantially identical to the Ideal Mimesys' Centrifugal Pump predicate device with respect to the basic function of an ordinary centrifugal pump that is propulsion of blood through the cardiopulmonary bypass circuit by centrifugal force. In addition the ECC.O air removal system (defoamer) replaces the air removal function of ordinary venous reservoirs in a way substantially equivalent to the Ideal Mimesys' Bubble Trap with respect to the main functions of an ordinary bubble trap that is separation and evacuation of gaseous emboli form the venous blood.

Data collected show that integration of the venous air removal device (defoamer) and of the centrifugal pump to the oxygenating module is advantageous in terms of lower operating blood volumes during priming procedures.

Therefore it can be concluded that ECC.O system duplicates the functionality of the separated predicate devices. Biocompatibility studies demonstrate that the device is biocompatible according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

Dideco S.r.l.
c/o Mr. Barry Sall
Senior Consultant
Parexel International
195 West Street
Waltham, MA 02451

Re: K050890
ECC.O, System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Hollow Fiber Oxygenator and Heat Exchanger
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type Cardiopulmonary Bypass Blood Pump
Regulatory Class: Class III (three)
Product Code: KFM
Dated: April 7, 2005
Received: April 8, 2005

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050890

Device Name: ECC.O System with Integrated Venous Air Removal, Centrifugal Blood Pump, Pump Bracket, Hollow Fiber Oxygenator and Heat Exchanger

Indications For Use:

The ECC.O is intended for use in patients who undergo surgical procedures requiring extracorporeal gas exchange support and blood temperature control with a maximum blood flow rate of 5 liters/minute. ECC.O must not be used longer than 6 hours. Contact with blood for longer periods is inadvisable. ECC.O is intended for use with the Stöckert Centrifugal Pump Console.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050890